Remarks

In the application, Claims 1-4 are pending. Examiner has rejected Claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Asai et al., EP1350511 translated version of WO 02/051412. Examiner has also rejected Claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over Asai et al., EP1350511 translated version of WO 02/051412 in view of Mehta et al., The Lancet 358, 2001 p527-533 (of record).

Applicants provide herewith amended Claims 1, 3 and 4. Applicants also provide below arguments believed to overcome Examiner's rejections in light of the amendments, and requiring reconsideration of the rejections by Examiner.

Amendments

Applicants have amended Claim 1 to delete the phrase "cerebrovascular aneurysm" and otherwise amend the claim as to form.

Applicants have also amended claims 3 and 4 to remove the phrase "cerebrovascular aneurysm," the term "optionally" and otherwise amend Claims 3 and 4 as to form. Applicants believe amendments to Claims 1, 3 and 4 and argument presented herein obviate Examiner's rejections for anticipation and/or obviousness based on Asai et al.

102(b) Rejection

Examiner has rejected Claims 1 and 2 as being anticipated by Asai et al. Applicants believe that the 102(b) rejection is improper because the instant application claims priority to May 05, 2003 which is less than one year following the first publication of the Asai et al reference on July 04, 2002 in Japanese, and later translated and published as EP 1350511 on October 08, 2003.

Applicants request reconsideration of the 102(b) rejection in view of the impropriety of a 102(b) rejection as discussed above, the amendment to Claim 1 deleting the phrase "cerebrovascular aneurysm," and on the basis of the limitation of the claim to coronary percutaneous intervention (PCI) as distinct from the generic disclosure of angioplasty in Asai et al.

Asai et al discloses the use of compound I in the treatment or prevention of diseases such as unstable angina pectoris, cerebral ischemic insult or restenosis due to angioplasty, but does not specifically disclose the use of compound I in conjunction with coronary angioplasty also known as PCI. Angioplasty is the common name for

procedures to widen blood vessels at various locations in the body of a patient. Angioplasty includes percutaneous coronary intervention (PCI), percutaneous transluminal angioplasty (PTA), percutaneous transluminal renal angioplasty (PTRA), and carotid angioplasty.

Applicants' claims are directed to the use of the compound of formula I in conjunction with the specific procedure of percutaneous coronary intervention (PCI) also known as coronary angioplasty as distinct from angioplasty in general. Applicants' present herein, selection claims directed to use of the compound of formula I specifically in conjunction with PCI from among the many uses disclosed in Asai et al.

For the foregoing reasons including the amendments presented herein, Applicants' respectfully request reconsideration of the rejection based on 35 U.S.C. 102(b).

35 U.S.C. 103(a) Rejection

Examiner has rejected Claims 1-4 under 35 U.S.C.103(a) as being unpatentable over Asai et al., EP1350511 translated version of WO 02/051412 in view of Mehta et al., The Lancet 358, 2001 p527-533 (of record).

Examiner has also rejected the claims as obvious over Smith et al. According to Examiner, Smith teaches "drugs of thienopyridines such as clopidogrel and ticlopidine are used with PCI procedure."

Applicants believe that the above disclosures notwithstanding, the present claims are unobvious due to the unexpectedly superior results obtained with the compound of formula I in conjunction with PCI in the TIMI TRITON-38 study. The TIMI TRITON-38 study compared prasugrel versus clopidogrel (the compound in the Mehta and Smith references) in a study of 13,608 patients with acute coronary syndromes undergoing PCI. Wiviott et al., in Prasugrel versus Clopidogrel in Patients with Acute Coronary Syndromes, N. England J. Med. 357(20) 2001 (2007) concluded that "[I]n patients with acute coronary syndromes with scheduled percutaneous coronary intervention, prasugrel (prasugrel is the non-proprietary name for the compound of formula I) therapy was associated with significantly reduced rates of ischemic events, including stent thrombosis, but with an increased risk of major bleeding, including fatal bleeding" (emphasis added). Specifically, the authors found that:

- the primary efficacy end point occurred in 12.1% of patients receiving clopidogrel and 9.9% of patients receiving prasugrel (hazard ratio for prasugrel vs. clopidogrel, 0.81; 95% confidence interval [CI], 0.73 to 0.90; P<0.001)
- significant reduction in the prasugrel group in the rates of myocardial infarction (9.7% for clopidogrel vs. 7.4% for prasugrel; P<0.001)
- urgent target-vessel revascularization (3.7% vs. 2.5%; P<0.001)
- stent thrombosis (2.4% vs. 1.1%; P<0.001)

Applicants submit that the above results showing clinically superior outcomes for the compound of formula I compared to clopidogrel in patients with acute coronary syndromes undergoing PCI were not suggested, taught or motivated by the prior art and could not have been predicted by one of ordinary skill in the art on the basis of any *apriori* knowledge.

Applicants believe that a prima facie obviousness rejection is overcome by the superior and unexpected results obtained in the TIMI TRITON-38 trial results disclosed by Wiviott et al. discussed above.

For all of the above reasons including the amendments made herein, Applicants respectfully request reconsideration of the rejections under 102(b) and 103(a).

Respectfully submitted,

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